

REMARKS**Interview Summary Record**

Applicants thank the Examiners for the discussions during the interview on June 21, 2011. The Examiners accepted Applicants' position that the amendments to the specification were not new matter for the reasons set forth on pages 6-7 of the reply filed on April 25, 2011. However, the Examiners questioned as whether torasemide remains crystalline in the final formulation. [The attached Rule 132 Declaration addresses and supports Applicants' position that the processing does not affect the crystallinity in the final product.] Applicants' Representative also discussed the various obviousness rejections of the claims set forth on pages 7-11 of the Reply filed on April 25, 2011.

Claim Rejections – 35 USC § 103

All remarks from the Reply filed on April 25, 2011, are herein incorporated by reference.

Maegerlein et al. in view of Tian et al.

The Examiner rejects claims 1-5 and 7-15 as being unpatentable over Maegerlein *et al.* as evidenced by Azarmi *et al.* in view of Tian *et al.* Applicants respectively traverse.

Maegerlein *et al.* state in paragraph [0001], lines 1-3 of the Specification:

The present invention relates to preparations of the active compound torasemide, in which the torasemide is present in essentially noncrystalline form. (emphasis added)

Paragraph [0008] Maegerlein *et al.* reads:

Accordingly, we have found that this object is achieved by storage-stable solid or semisolid preparations in which the torasemide is present in essentially noncrystalline form. Preferably, the preparations are a so-called “solid solution”. The preparations,

however, can also contain amorphous agglomerates dispersed homogeneously in the binder matrix, the size of such agglomerates preferably being in the region of $\leq 1\mu\text{m}$. (emphasis added)

Claim 1 of Maegerlein *et al.* also recites:

1. A stable solid or semisolid pharmaceutical preparation, comprising torasemide in essentially noncrystalline form. (emphasis added)

Accordingly, the torasemide of Maegerlein *et al.* is not present in crystalline form, as it is in the instant invention, but instead is present in amorphous form. Consequently, the skilled artisan would not have turned to Maegerlein *et al.* to produce a tablet where the torasemide was in crystalline form and would not have had a reasonable expectation of success in so doing. The secondary references do not make up for the deficiencies of the Maegerlein *et al.* reference.

Finally, the attached Rule 132 Declaration addresses the Examiner's concerns that the crystallinity of the claimed composition is affected by processing used to make the tablet. The Declaration shows that crystallinity is not affected by the process used to make the tablet. Accordingly, this rejection should be withdrawn.

Maegerlein et al., Tian et al. and Pankhania et al.

As noted above, the combination of Maegerlein *et al.* and Tian *et al.* does not make the instant invention obvious because the claimed invention contains torasemide in crystalline form. The Pankhania *et al.* reference does not cure the defects left by the combination of Maegerlein *et al.* and Tian *et al.* Consequently, Applicants request withdrawal of the rejection.

Berner et al. and Kaplan

The Examiner has rejected claims 1-15 as unpatentable over Berner *et al.* in view of Kaplan. Applicants respectfully traverse.

Applicants submit that the Examiner fails to establish a *prima facie* case of obviousness. More specifically, the Examiner has impermissibly used hindsight to make the instant rejection, using the claims as a "template" upon which to assemble references, each reciting an element of the claim.

As discussed during the interview, the Examiner's "templating" approach is not appropriate. That is, Applicants submit that there are a vast number of active ingredients, polymers, binders, lubricants, disintegrants, fillers, *etc.* presented in Berner *et al.* and an extraordinarily broad and superficial disclosure of torasemide drugs presented in the review article entitled "Diuretics as a Basis of Antihypertensive Therapy An Overview" authored by Kaplan. The Examiner relies upon Kaplan stating "... Berner *et al.* do not exemplify a formulation comprising torasemide. However, this deficiency is cured by Kaplan" (Office Action page 8, last paragraph). But there is no actual disclosure of a torasemide formulation in the Kaplan reference.

Kaplan merely states:

Therefore, I strongly recommend the use of longer acting diuretics for those with good renal function and either metolazone^[23] or perhaps torasemide^[24] for those with impaired renal function who need stronger diuretics" (see page 23, right column, first full paragraph, second sentence).

Kaplan then simply recites a statement from the 1997 Sixth Report of the US Joint National Committee regarding what "the optimal formulation should provide (see page 23, right column,

second full paragraph, second sentence). This type of disclosure clearly does not present “a formulation comprising torasemide.”

The type of obviousness rejection made by the Examiner in the present application has been repeatedly rebuked by the courts. See, e.g. *Sensonics, Inc. v. Aerisonic Corp.*, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996):

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed.Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil* , 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed.Cir. 1985).

It is not sufficient to establish *prima facie* obviousness by merely listing a set of references that together set forth each of the elements of the claim individually. A claim composed of several elements is not proved obvious simply by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* Unless the combined prior art references suggest the claimed invention, either explicitly or implicitly, the Examiner must present a “*convincing line of reasoning* as to why one of ordinary skill in art would have found the claimed invention to have been obvious.” *Ex parte Rorher*, Appeal 2009-001292, 5 (BPAI, February 5, 2010) *citing Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (BPAI 1985)(emphasis added, internal quotations omitted).

Furthermore, the Examiner is not permitted to merely extract from cited references those teachings that support a conclusion of obviousness. Rather, the references must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983):

In its consideration of the prior art, however, the district court erred in ...considering the references in less than their entireties, i.e., in disregarding disclosures in the references that diverge from and teach away from the invention at hand. *In re Kuderna*, 426 F.2d 385, 165 USPQ 575 (CCPA 1970).

Since the Examiner has improperly used a "templatizing," hindsight-based approach to formulating the instant rejection, it is plain that the combination of Berner *et al.* and Kaplan fails to establish *prima facie* obviousness of instant claims 1, 2, 7, 8 and 11-23. Accordingly, the instant rejection should be withdrawn.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Registration No. 32181, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: January 5, 2012

Respectfully submitted,

By 

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Attachment: Executed Declaration Under 37 C.F.R. 1.132